Remarks

Prior to entry of this amendment, claims 1-14 are pending in the application. Claims 1-3 and 7-12 are canceled herein, in order to expedite allowance of this application. Claims 4 and 14 are amended herein. New claims 15-20 are added herein.

Support for the amendments to claim 4 can be found throughout the specification, such as in the original claims and on page 5, lines 15 to page 9, line 9, and on page 34, line 9 to page 35, line 19. Claim 14 is amended to correct a typographical error.

New claims 15-20 are added herein. New claims 15-17 depend from independent claim 14; and each of claims 15-20 is directed to a vaccine comprising an individual polypeptide sequence included in claim 14. New claims 18-20 are directed to vaccines comprising lapidated forms of an individual polypeptide, and parallel claim 16. Thus, all of this subject matter encompassed by new claims 15-20 already has been searched by the U.S. PTO for the examination of previously pending claims 14 and 16.

After entry of this amendment, **claims 4, 5, 6, 13-20 are pending.** Applicants believe that the amendment of claims 4 and 14, and the cancellation of claims 1-3 and 7-12 place the claims in condition for allowance, which action is requested.

Rejection Under 35 U.CS.C. § 112, first paragraph

Claims 4-6 and 13-14 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly the specification, while being enabling for a protein of 16 kDa as determined by SDS PAGE, and for vaccines including specified sequence identifiers, is not enabling for variants of a protein sequence. Applicants respectfully disagree with this rejection.

However, Applicants submit that the previous amendment of the claims (see the response dated June 22, 2005) rendered this rejection moot. The claims as pending are directed to vaccines comprising an isolated protein comprising an amino acid sequence set forth as SEQ ID NO: 2, an amino acid sequence set forth as SEQ ID NO:4, or an amino acid sequence set forth as SEQ ID NO: 4. "Fragment" and "variant" are not included in any of claims 4-6 and 13-14. The Office action appears to assert that the phrase "said protein comprising an amino acid sequence of one of SEQ ID NO: 2,

SEQ ID NO: 4, or SEQ ID NO: 6" encompasses fragments of these specific sequences. Applicants fail to understand how a protein comprising an amino acid sequence of a full length protein (SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6) could include a fragment of this protein.

Applicants have made every attempt to amend the claims to be in condition for allowance. Applicants believe the pending claims are directed to vaccines including polypeptides comprising an amino acid sequence set forth as SEQ ID NO: 2, set forth as SEQ ID NO: 4, or set forth as SEQ ID NO: 6 (full-length sequences for OspA). Thus, reconsideration and withdrawal of the rejection is respectfully requested.

Applicants representative contacted Examiner Ford on November 16, 2005 and November 18, 2005 to determine if there were specific amendments required by the Examiner to clarify the claimed subject matter. However, the Examiner indicated that she was unable to discuss this application before November 28, 2005. In the unlikely event that the Examiner believes the amended claims still encompass variants or fragments, the Applicants request a telephone interview with Examiner Ford and Examiner Smith to discuss acceptable claim language.

Rejection Under 35 USC § 102

Claims 4, 6 and 14 were rejected under 35 USC § 102 because the claimed subject-matter allegedly is anticipated by Barnes et al. Applicants respectfully disagree with this rejection.

Barnes et al disclosed a composition comprising proteins of 56 kDa, 30 kDa and 20 kDa isolated from *Piscirickettsia salmonis*. The Office action alleges that since proteins of 56, 30 and 20 kDa have been isolated from *Piscirickettsia salmonis*, that SEQ ID NO: 2 must be inherent in these isolated proteins. Applicants respectfully disagree with this assertion.

As disclosed in the specification, isolated OspA protein has a molecular weight of 16 kDa. It is well known in the art that proteins of different molecular weights can be readily visualized on a gel using SDS PAGE. Using SDS PAGE, it can be demonstrated that a protein having a molecular weight of 16 kDA protein is distinct from a protein having a molecular weight of 20 kDa protein, 30 kDa or a 56 kDa.

Attached as Exhibit A is a digital image (marked "A") showing the expression, lipidation and Western Blot analysis of OspA. Panel A shows SDS PAGE of expression of proteins in *E. coli*,

including *E. coli* epxression OspA (lane 4). The position of molecular weight markers (showing the positions of 16.5, 25, 32.5, 47.5, 62, 83 and 175 kDa) are indicated on the left side of the image.

As demonstrated by the position of the molecular weight markers, using SDS PAGE, a 16.5 kDa protein is clearly distinguishable from a 12, 30, or 56 kDa protein. As can be seen in lanes 1-4, proteins of a variety of molecular weights are expressed in *E. Coli*. Lane 4 shows the pattern of protein expression when pET-Δ17E2 (OspA) expression is induced in E.Coli (at 42 °C). In lane 4, a specific band is detected just below the 16.5 kDA marker. By comparison to the molecular weight markers, it can be seen that the expressed protein does not have a molecular weight of 20, 30 or 56 kDA.

This Exhibit demonstrates that OspA proteins having an amino acid sequence set forth as SEQ ID NO: 2, SEQ ID NO: 4, or SEQ ID NO: 6 will be visualized as a 16 kDA protein on an SDS PAGE gel, and will not be visualized as proteins having a molecular weight of 20 kDa, 30 kDa or a 56 kDa. Thus, the proteins isolated by Barnes et al., which have molecular weights of 20 kDa, 30 kDa or 56 kDa must be different proteins than OspA (and must have a different amino acid sequence). Thus, the proteins disclosed by Barnes et al. cannot have an amino acid sequence set forth as SEQ ID NO: 2.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 4, 6, 13 and 14 are rejected under 35 U.S.C. § 102 as allegedly being anticipated by Rubenfield et al. Applicants respectfully disagree with this rejection.

Rubenfield et al. discloses a polypeptide and nucleic acid sequences derived from *Pseudomonas aeruginosa*. Rubenfield et al. does not disclosed polypeptides isolated from *Piscirickettsia salmonis*. A comparison of SEQ ID NO: 2 with a polypeptide sequence disclosed in Rubenfield et al. was referred to in the Office action as forming the basis for this rejection.

This comparison prepared by the U.S. PTO shows that the amino acid sequence disclosed by Rubenfield et al. is only 15.4% identical to SEQ ID NO: 2. Thus, the sequence disclosed by Rubenfield et al. differs dramatically from SEQ ID NO: 2. In fact, the amino acid sequence disclosed in Rubenfield et al. differs by more than 84% from SEQ ID NO: 2. Applicants believe that the sequence comparison prepared by the U.S. PTO clearly indicates that Rubenfield et al. does not disclose SEQ ID NO: 2, and thus cannot anticipate, nor render obvious, claims 4, 6, 13 and 14.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103

Claims 4, 6, 13 and 14 are rejected under 35 U.S.C. § 103 as allegedly being obvious over Rubenfield et al. in view of Mond et al. Applicants respectfully disagree with this rejection.

As discussed above, Rubenfield et al disclosed an amino acid sequence that is dramatically different from SEQ ID NO: 2, the amino acid sequences differ by 84.6% over the length of these proteins. Mond et al disclose lipidated polypeptides to promote an immune response.

However, Mond et al. does not make up for the deficiencies of Rubenfield et al. Specifically, Mond et al. does not disclose vaccines including polypeptides that include an amino acid sequence set forth as SEQ ID NO: 2, SEQ ID NO: 4 or SEQ ID NO: 6, nor does Mond et al. disclose a vaccine that includes a polypeptide having an amino acid sequence set forth as SEQ ID NO: 2, SEQ ID NO: 4 or SEQ ID NO: 6. Thus, claims 4, 6, 13 and 14 are not obvious over Rubenfield et al., alone or in combination with Mond et al.

Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

It is respectfully submitted that the present claims are in a condition for allowance. If any issues remain prior to the issuance of a Notice of Allowance, Examiner Ford and Examiner Smith are requested to contact the undersigned in order to arrange a telephone interview. It is believed that a brief discussion of the merits of the present application will expedite prosecution and allowance of the claims.

Respectfully submitted,

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